

PCT

LD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

|  |  |           |   |
|--|--|-----------|---|
| (51) International Patent Classification <sup>7</sup> :<br><b>A61M 16/00</b>   |  | <b>A1</b> | (11) International Publication Number: <b>WO 00/67826</b>   |
|  |  |           | (43) International Publication Date: 16 November 2000 (16.11.00)  |
| <p>(21) International Application Number: PCT/AU00/00411</p> <p>(22) International Filing Date: 5 May 2000 (05.05.00)</p> <p>(30) Priority Data:<br/>PQ 0198 6 May 1999 (06.05.99) AU</p> <p>(71) Applicant (for all designated States except US): RESMED LIMITED [AU/AU]; 97 Waterloo Road, North Ryde, NSW 2113 (AU).</p> <p>(72) Inventors; and</p> <p>(75) Inventors/Applicants (for US only): BERTHON-JONES, Michael [AU/AU]; 7, Leonay Parade, Leonay, NSW 2750 (AU). WICKHAM, Peter, John, Deacon [AU/AU]; 20 Hampden Road, Five Dock, NSW 2046 (AU).</p> <p>(74) Agent: SPRUSON &amp; FERGUSON; GPO Box 3898, Sydney, NSW 2001 (AU).</p>   |  |           | <p>(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b><br/>With international search report.</p> |
| <p>(54) Title: CONTROL OF SUPPLIED PRESSURE IN ASSISTED VENTILATION</p> <p>(57) Abstract</p> <p>Methods and apparatus for detecting the occurrence of a potential or actual overpressure during assisted ventilation are described. A blower (10) supplies pressurised gas to a conduit (12), and in turn to a patient mask (11) for connection with the entrance of a patient's airways. A pressure sensor (17, 18) detects the delivered pressure in the mask (11), which is provided to a controller (16). The controller (16) has operation over the blower (10) by way of a servo (19) and motor (20). The controller (16) determines a relatively longterm average of the pressure signal, and compares it against a threshold value (40). If the threshold value is approached or exceeded, the controller (16) controls the blower (10) and thus the supplied pressure to the patient. The effect of the control can be to limit or reduce the supplied gas pressure. The relatively longterm average can be of the order of minutes, or taken over ten or more breaths.</p> |  |           |   |

*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

|    |                          |    |  |    |  |    |                          |
|----|--------------------------|----|--|----|--|----|--------------------------|
| AL | Albania                  | ES | Spain                                    | LS | Lesotho                                      | SI | Slovenia                 |
| AM | Armenia                  | FI | Finland                                  | LT | Lithuania                                    | SK | Slovakia                 |
| AT | Austria                  | FR | France                                   | LU | Luxembourg                                   | SN | Senegal                  |
| AU | Australia                | GA | Gabon                                    | LV | Latvia                                       | SZ | Swaziland                |
| AZ | Azerbaijan               | GB | United Kingdom                           | MC | Monaco                                       | TD | Chad                     |
| BA | Bosnia and Herzegovina   | GE | Georgia                                  | MD | Republic of Moldova                          | TG | Togo                     |
| BB | Barbados                 | GH | Ghana                                    | MG | Madagascar                                   | TJ | Tajikistan               |
| BE | Belgium                  | GN | Guinea                                   | MK | The former Yugoslav<br>Republic of Macedonia | TM | Turkmenistan             |
| BF | Burkina Faso             | GR | Greece                                   |    |  | TR | Turkey                   |
| BG | Bulgaria                 | HU | Hungary                                  | ML | Mali   | TT | Trinidad and Tobago      |
| BJ | Benin                    | IE | Ireland                                  | MN | Mongolia                                     | UA | Ukraine                  |
| BR | Brazil                   | IL | Israel                                   | MR | Mauritania                                   | UG | Uganda                   |
| BY | Belarus                  | IS | Iceland                                  | MW | Malawi                                       | US | United States of America |
| CA | Canada                   | IT | Italy                                    | MX | Mexico                                       | UZ | Uzbekistan               |
| CF | Central African Republic | JP | Japan                                    | NE | Niger  | VN | Viet Nam                 |
| CG | Congo                    | KE | Kenya                                    | NL | Netherlands                                  | YU | Yugoslavia               |
| CH | Switzerland              | KG | Kyrgyzstan                               | NO | Norway                                       | ZW | Zimbabwe                 |
| CI | Côte d'Ivoire            | KP | Democratic People's<br>Republic of Korea | NZ | New Zealand                                  |    |                          |
| CM | Cameroon                 |    | Republic of Korea                        | PL | Poland                                       |    |                          |
| CN | China                    | KR | Republic of Korea                        | PT | Portugal                                     |    |                          |
| CU | Cuba                     | KZ | Kazakhstan                               | RO | Romania                                      |    |                          |
| CZ | Czech Republic           | LC | Saint Lucia                              | RU | Russian Federation                           |    |                          |
| DE | Germany                  | LI | Liechtenstein                            | SD | Sudan  |    |                          |
| DK | Denmark                  | LK | Sri Lanka                                | SE | Sweden                                       |    |                          |
| EE | Estonia                  | LR | Liberia                                  | SG | Singapore                                    |    |                          |

## CONTROL OF SUPPLIED PRESSURE IN ASSISTED VENTILATION

### Field of the Invention

5           This invention relates to Non Invasive Positive Pressure Ventilation (NIPPV) treatment apparatus for the provision of assisted ventilation. Particularly, the invention concerns the control of treatment pressure supplied to a subject.

### Background Art

10           NIPPV apparatus function to supply a patient with a supply of clean breathable gas (usually air, with or without supplemental oxygen) at a therapeutic pressure or pressures, at appropriate times during the subject's breathing cycle. The therapeutic pressure is also known as the ventilation pressure.

15           NIPPV apparatus typically include a flow generator, an air filter, a mask, an air delivery conduit connecting the flow generator to the mask, various sensors and a microprocessor-based controller. The flow generator may include a servo-controlled motor and an impeller. The flow generator may also include a valve capable of  
20   discharging air to atmosphere as a means for altering the pressure delivered to the patient as an alternative to motor speed control. The sensors measure, amongst other things, motor speed, gas volumetric flowrate and outlet pressure. The apparatus may optionally include a humidifier in the air delivery circuit. The controller may include data storage capacity with or without integrated data retrieval and display functions.

25           In this specification, NIPPV apparatus will be referred to as "assisted ventilation devices" which, in the broadest form, need not include all of the component features mentioned above.

30           Assisted ventilation devices are used for the treatment of many conditions, for example respiratory insufficiency or failure due to lung, neuromuscular or musculoskeletal disease and diseases of respiratory control.

35           Common to all forms of assisted ventilation is the need to control the pressure being applied to the patient. It is a known prior art technique to detect the peak pressure

and compare it against a maximum threshold value. If the threshold value is exceeded an alarm state occurs, and corrective action may be taken. This corrective action can be a short-term reduction in supplied pressure, followed by an increase back to the previous pressure.

5

### **Disclosure of the Invention**

The present invention is directed to providing an alternative, advantageous approach to the problem of overpressure.

10

The invention discloses a method for controlling operation of an assisted ventilation device supplying pressurised gas to a patient, the method comprising the steps of:

15 determining a relatively longterm average of pressure of gas supplied to said patient; and

controlling the pressure supplied by said ventilation device with regard to said longterm average.

20 The invention further discloses a method for detecting the occurrence of a potential or actual overpressure during assisted ventilation, comprising the steps of determining a relatively longterm average of ventilation pressure, and determining whether the average approaches or exceeds a threshold value as being indicative of a potential or actual overpressure occurring.

25 The invention further discloses a method for controlling operation of an assisted ventilation device supplying pressurised gas to a patient, the method comprising the steps of:

measuring the currently delivered pressure;

determining a relatively longterm average of the measured pressure;

30 comparing said average against a threshold value; and

if the threshold value is approached or exceeded, controlling the pressure supplied by the device.

35 The invention yet further discloses assisted ventilation apparatus for detecting a potential or actual overpressure condition, comprising:

a blower to supply pressurised gas to a conduit, and in turn to a patient mask for connection with the entrance to a patient's airways:

a pressure sensor to detect the delivered pressure of gas in the conduit or at the mask, and provide a signal thereof; and

5 a controller receiving said pressure signal and having control over operation of the blower and operable to determine a relatively longterm average of the pressure signal and to control the supplied pressure with regard to said longterm average.

The invention yet further discloses assisted ventilation apparatus for detecting a  
10 potential or actual overpressure condition, comprising:

a blower to supply pressurised gas to a conduit, and in turn to a patient mask for connection with the entrance to a patient's airways;

a pressure sensor to detect the delivered pressure of gas in the conduit or at the mask, and provide a signal thereof; and

15 a controller, receiving the pressure signal and having control over operation of the blower, and operable to determine a relatively longterm average of the pressure signal, compare the average against a threshold value, and if the threshold value is approached or exceeded, to control the blower and thus the supplied pressure.

20 In one preferred form, an alarm state exists when said threshold is approached or exceeded, and on the occurrence of an alarm state, the assisted ventilation apparatus issues an alarm. Additionally or alternatively, the blower can be controlled to be switched-off or to be placed in a low pressure standby mode (for example 4 cmH<sub>2</sub>O).

25 The invention further discloses a method for controlling operation of an assisted ventilation device supplying pressurised gas to a patient, the method comprising the steps of:

determining a relatively longterm average of supplied pressure; and

controlling said supplied pressure as a function of a waveform template, a  
30 target patient ventilation and said longterm average.

In relation to control of supplied pressure, the blower can be controlled to limit or reduce the supplied pressure. The reduction can be a non-linear function of time and/or pressure. Particularly, the degree of control can be stronger/greater as the  
35 threshold value is approached.

The longterm average can, in one form, be of the order of minutes. Alternatively, the average can be over ten or more breaths.

5           The threshold can be required to be exceeded for a minimum period of time before the alarm state is assessed as occurring.

10           The invention is advantageous in that it approaches the problem of overpressure from a relatively longer time scale than in the prior art. This is considered to be a more appropriate approach to the medical conditions that attend overpressure in assisted ventilation. For example, sustained overpressure causes a decrease in cardiac output, which would go largely untreated by the prior art arrangement discussed above.

#### 15   **Brief Description of the Drawings**

Fig. 1 is a schematic block diagram of a representative assisted ventilation device, in the form of NIPPV apparatus;

Fig. 2 is a schematic block diagram of an overpressure detection circuit;

20           Fig. 3 shows traces of treatment pressure with time and the operation of an embodiment of the invention; and

Fig. 4 shows further traces of treatment pressure with time and the operation of an embodiment of the invention.

#### 25   **Description of Preferred Embodiments and Best Mode**

An assisted ventilation device embodying one form of the invention is shown in Fig. 1, in which a blower comprising a motor 20 and an impeller 10, supplies breathable gas to a mask 11 for communication with a subject's airway via a delivery tube 12 and exhausting to atmosphere via an exhaust 13. Airflow at the mask 11 is measured using a pneumotachograph 14 and a differential pressure transducer 15. The mask flow signal from the transducer 15 is sampled by a microprocessor 16. Mask pressure is measured at a port 17 using a pressure transducer 18. The pressure signal from the transducer 15 is also sampled by the microprocessor 16. The microprocessor 35 16 sends an instantaneous mask pressure request signal to a servo 19, which compares

the pressure request signal with the actual pressure signal from the transducer 18 to control a motor 20 driving the impeller 10. The microprocessor's settings can be adjusted via a serial port 21.

5 It is to be understood that the mask could equally be replaced with a tracheotomy tube, endotracheal tube, nasal pillows, or other means of making a sealed connection between the air delivery means and the subject's airway.

10 In general terms, the invention is concerned with determining a relatively longterm average of ventilation pressure and avoiding occurrence of overpressure with regard thereto.

In one embodiment, the microprocessor 16 determines the long-term average of the actual treatment pressure,  $\bar{P}$ , and compares this against a threshold or maximum  
15 value,  $\bar{P}_{\max}$ . If the threshold value is exceeded then corrective action may be taken.

The corrective action can be to issue an alarm, to switch-off the assisted ventilation device, to reduce the treatment pressure, or to control the blower in a more complex manner, an example of which is described in more detail below.

20 As shown in Fig. 2, the circuitry 30 receives a signal from the pressure transducer 15 indicative of the pressure in the air delivery conduit 12. The signal is amplified by an operational amplifier 32, then low-pass filtered 34 with a time constant of approximately one minute. Longer or shorter time constants would be appropriate  
25 depending on how long it was considered safe for the subject to be exposed to a relatively high mean pressure. In one embodiment, the time constant can be varied by way of an operator accessible control. The low-pass filtered signal passes to a comparator 36 where it is compared with a reference pressure signal corresponding to 15 cmH<sub>2</sub>O, representing  $\bar{P}_{\max}$ . The output from the comparator passes to both the  
30 servo 19 and a resettable monostable/one-shot 38. The resettable monostable/one-shot 38 is set to 30 seconds. Longer or short time periods would be suitable for specific assisted ventilation applications.

If the output from the comparator 36 is 'true', an indication that the low-pass  
35 filter signal exceeds  $\bar{P}_{\max}$ , a "reduce" pressure signal is sent to the servo 19 (shown in

Fig. 1) on line 42. At this point, the resettable monostable/one-shot 38 starts to count down. If the count down reaches zero, then a stop signal is sent to the servo 19 on line 44. The count determines an adjustable tolerance on how long the alarm state has occurred before corrective action is taken. If the output from the comparator 36 is  
 5 "false", there is no alarm state, and the resettable monostable/one-shot 38 is reset.

In another embodiment, implemented in software, the avoidance of overpressure is approached as the continuous monitoring of pressure as a function of the longterm average of the pressure. Referring once again to Fig. 1, the microprocessor 16 receives a  
 10 signal representing mask pressure from the transducer 18. The microprocessor 16 controls the servo 19 such that the desired treatment pressure achieved satisfies the following equation:

$$P = P_0 + k.A.f(v,t) \quad [1]$$

15 where:

$P$  is the pressure setting for the blower (degree of support) (cmH<sub>2</sub>O);

$P_0$  is a constant, the baseline pressure, chosen, for example, to keep the upper airway open, or to balance intrinsic PEEP (cmH<sub>2</sub>O).

20 In one form,

$$k = 1. \quad [2a]$$

In other forms,

$$k = k', \text{ low pass filtered with time constant of 5 seconds} \quad [2b]$$

where:

$$25 \quad k' = \begin{cases} 0, & \bar{p} \geq 15 \text{ cmH}_2\text{O} \\ 0.1, & \bar{p} = 14.9 \text{ cmH}_2\text{O} \\ 1, & \bar{p} \leq 14.5 \text{ cmH}_2\text{O} \end{cases} \quad [3]$$

and linearly in between.

The purpose of making  $k$  nonlinear on  $\bar{p}$  is to provide strong control as  $\bar{P}_{\max}$   
 30 is approached, with less effect further away from  $\bar{P}_{\max}$ . The purpose of low pass filtering is to reduce distortion of the within-breath pressure-time profile.

The pressure modulation amplitude,  $A$  (cm H<sub>2</sub>O) is given by:



$$A = g \int (\dot{V}_e - V_{TGT}) dt \quad [4]$$

where  $g$  is a constant,  $\dot{V}_e$  is the minute ventilation, and  $V_{TGT}$  is the target ventilation.  $A$  may be truncated to lie between  $A_{max}$  and  $A_{min}$ .

$f$  is a function of at least one of time,  $t$ , and respiratory airflow,  $v$ , chosen to produce the desired pressure waveform. A range of functions is known to those skilled in the art. One example function corresponding to a spontaneous mode bi-level ventilator is:

$$f(v, t) = \begin{cases} 1, & v > 0 \\ 0 & \text{otherwise} \end{cases} \quad [5a]$$

Another example function is:

$$f(v, t) = \begin{cases} 1, & t' < T_i \\ 0, & \text{otherwise} \end{cases} \quad [5b]$$

where:

$$t' = t \text{ modulo } T_{tot}$$

$$T_i = \text{duration of inspiration}$$

$$T_{tot} = \text{duration of a breath}$$

This corresponds to a "timed-mode" bilevel ventilator, with

$$P = P_o \text{ during expiration; and}$$

$$P = P_o + A \text{ during inspiration}$$

A number of simulations have been performed to demonstrate an embodiment of the invention in practise.

In Fig. 3, there is a sustained rise in peak pressure. In the top trace is shown the effect without the use of the present invention. The mean pressure exceeds a chosen  $\bar{P}_{max}$  of 15 cmH<sub>2</sub>O, which is undesirable. In the second trace, this is corrected by an embodiment of the invention, where the mean pressure is kept close to  $\bar{P}_{max}$ . The bottom trace shows the factor " $k$ ", and how it decreases from unity to approximately 0.5.

In Fig. 4, there is a transient rise in peak pressure. In the top trace, even without the practise of invention, the mean pressure closely approaches but does not exceed  $\bar{P}_{\max}$ , which is permissible, even though the instantaneous pressure goes very  
5 high. With the invention practised, (second trace), the resultant pressure is little affected, because  $k$  remains close to unity (bottom trace)

In this embodiment, as the mean pressure threshold is approached, the degree of assistance is gradually reduced or limited. In another embodiment, both the baseline  
10 pressure,  $P_0$ , and amplitude of ventilatory support,  $A$ , are progressively reduced as the mean pressure,  $\bar{P}$ , approaches the desired threshold pressure,  $\bar{P}_{\max}$ .

The invention has been described with reference to a number of non-limiting examples, and it will be appreciated that the invention can be embodied in numerous  
15 other forms.

**Claims:**

1. A method for controlling operation of an assisted ventilation device supplying pressurised gas to a patient, the method comprising the steps of:  
5 determining a relatively longterm average of pressure of gas supplied to said patient; and  
controlling the pressure supplied by said ventilation device with regard to said longterm average.
- 10 2. A method for detecting the occurrence of a potential or actual overpressure during assisted ventilation, comprising the steps of:  
determining a relatively longterm average of ventilation pressure; and  
determining whether the average approaches or exceeds a threshold value as being indicative of a potential or actual overpressure occurring.
- 15 3. A method as claimed in claim 2, comprising the further step of issuing an alarm upon the determination of a potential or actual overpressure occurring.
- 20 4. A method for controlling operation of an assisted ventilation device supplying pressurised gas to a patient, the method comprising the steps of:  
measuring the currently delivered pressure;  
determining a relatively longterm average of the measured pressure;  
comparing said average against a threshold value; and  
if the threshold value is approached or exceeded, controlling the pressure  
25 supplied by the device.
5. A method as claimed in claim 4, wherein said controlling step includes limiting or reducing supplied gas pressure to the patient.
- 30 6. A method as claimed in claim 5, wherein, for the case of reducing supplied gas pressure, the reducing step is a non-linear function of time and/or pressure.
7. A method as claimed in claim 6, wherein the degree of reduction is  
35 greater as said threshold value is approached.

8. A method as claimed in any one of claims 4 to 7, wherein, for the case of said longterm average exceeding said threshold, said determining step includes a condition that said excess must occur for a minimum period of time before it is  
5 determined that a potential or actual overpressure is occurring.

9. A method for controlling operation of an assisted ventilation device supplying pressurised gas to a patient, the method comprising the steps of:  
determining a relatively longterm average of supplied pressure; and  
10 controlling said supplied pressure as a function of a waveform template, a target patient ventilation and said longterm average.

10. A method as claimed in claim 9, wherein said function is given by:

15 
$$P = P_0 + k.A.f(v,t)$$

where:

$P$  is said supplied pressure,

$P_0$  is a constant pressure,

$K$  is a function of said longterm average,

20  $A$  is a function of said target patient ventilation, and

$f(v,f)$  represents said waveform template.

11. A method as claimed in claim 9, wherein, in said controlling step, when said longterm average approaches a threshold value, strong control of said  
25 supplied pressure is provided.

12. A method as claimed in any one of claims 4 to 11, wherein said longterm average is of the order of minutes.

30 13. A method as claimed in any one of claim 4 to 11, wherein said longterm average is taken over ten or more breaths.

14. Assisted ventilation apparatus for detecting a potential or actual overpressure condition, comprising:

a blower to supply pressurised gas to a conduit, and in turn to a patient mask for connection with the entrance to a patient's airways:

a pressure sensor to detect the delivered pressure of gas in the conduit or at the mask, and provide a signal thereof; and

5 a controller receiving said pressure signal and having control over operation of the blower and operable to determine a relatively longterm average of the pressure signal and to control the supplied pressure with regard to said longterm average.

15 15. Assisted ventilation apparatus as claimed in claim 14, wherein said controller controls the supplied pressure as a function of a waveform template, a target patient ventilation and said longterm average.

16. Assisted ventilation apparatus for detecting a potential or actual overpressure condition, comprising:

15 a blower to supply pressurised gas to a conduit, and in turn to a patient mask for connection with the entrance to a patient's airways;

a pressure sensor to detect the delivered pressure of gas in the conduit or at the mask, and provide a signal thereof; and

20 a controller, receiving the pressure signal and having control over operation of the blower, and operable to determine a relatively longterm average of the pressure signal, compare the average against a threshold value, and if the threshold value is approached or exceeded, to control the blower and thus the supplied pressure.

25 17. Apparatus as claimed in claim 16, wherein said controller controls the supplied pressure by limitation or reduction.

18. Apparatus as claimed in claim 17, wherein, for the case of reducing supplied pressure, the controller reduces the pressure as a non-linear function of time and/or pressure.

30

19. Apparatus as claimed in claim 18, wherein the degree of reduction by the controller is greater as said threshold value is approached.

35 20. Apparatus as claimed in any one of claims 16 to 19, wherein, for the case of said longterm average exceeding said threshold, the controller operates subject

to the condition that the time in excess must be greater than a minimum period of time before it is determined that a potential or actual overpressure is occurring.

21. Apparatus as claimed in any one of claims 16 to 20, further  
5 comprising alarm signalling means, coupled to said controller, for indicating that an alarm state exists if the threshold value is approached or exceeded.

22. Apparatus as claimed in any one of claims 14 to 21, wherein said  
controller determines the longterm average in the order of minutes.

10

23. Apparatus as claimed in any one of claims 14 to 21, wherein said  
controller determines the longterm average over ten or more breaths.

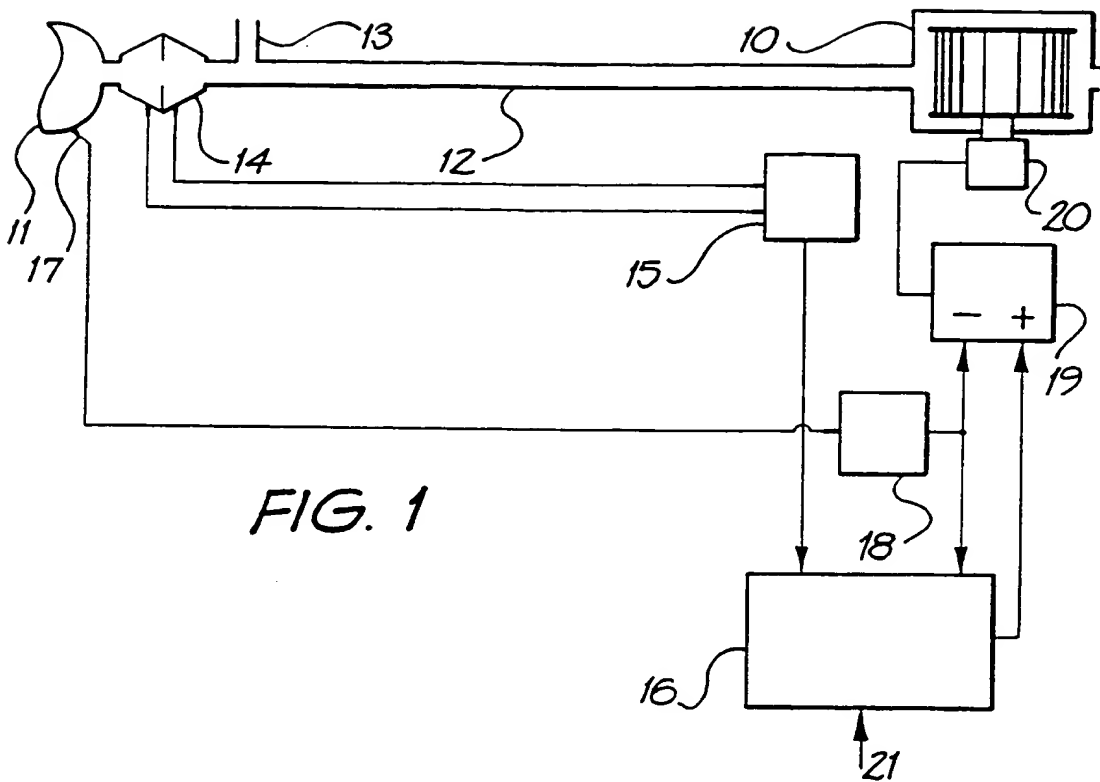


FIG. 1

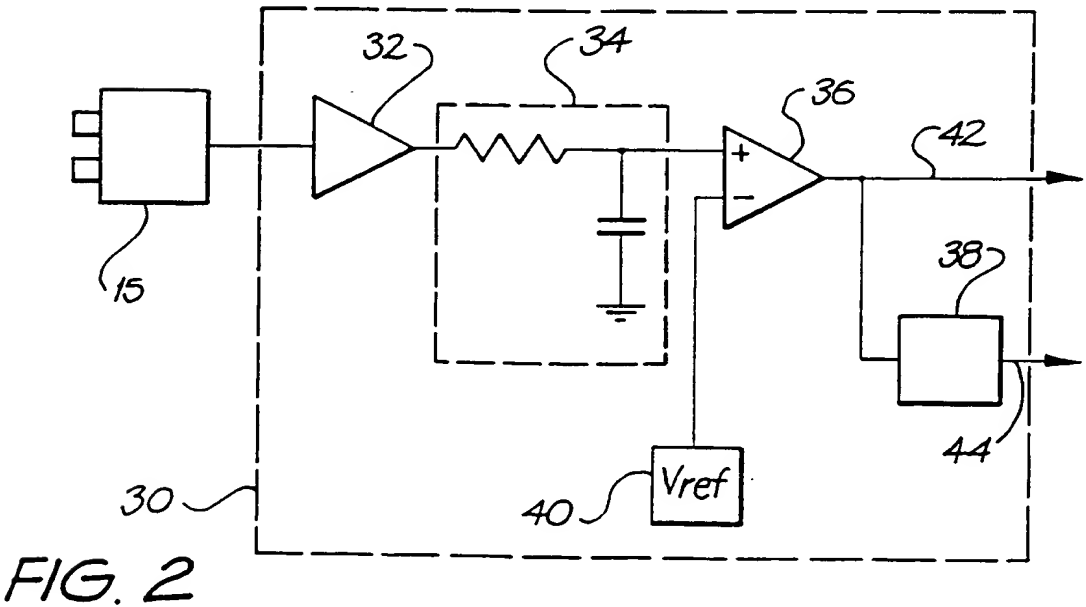


FIG. 2

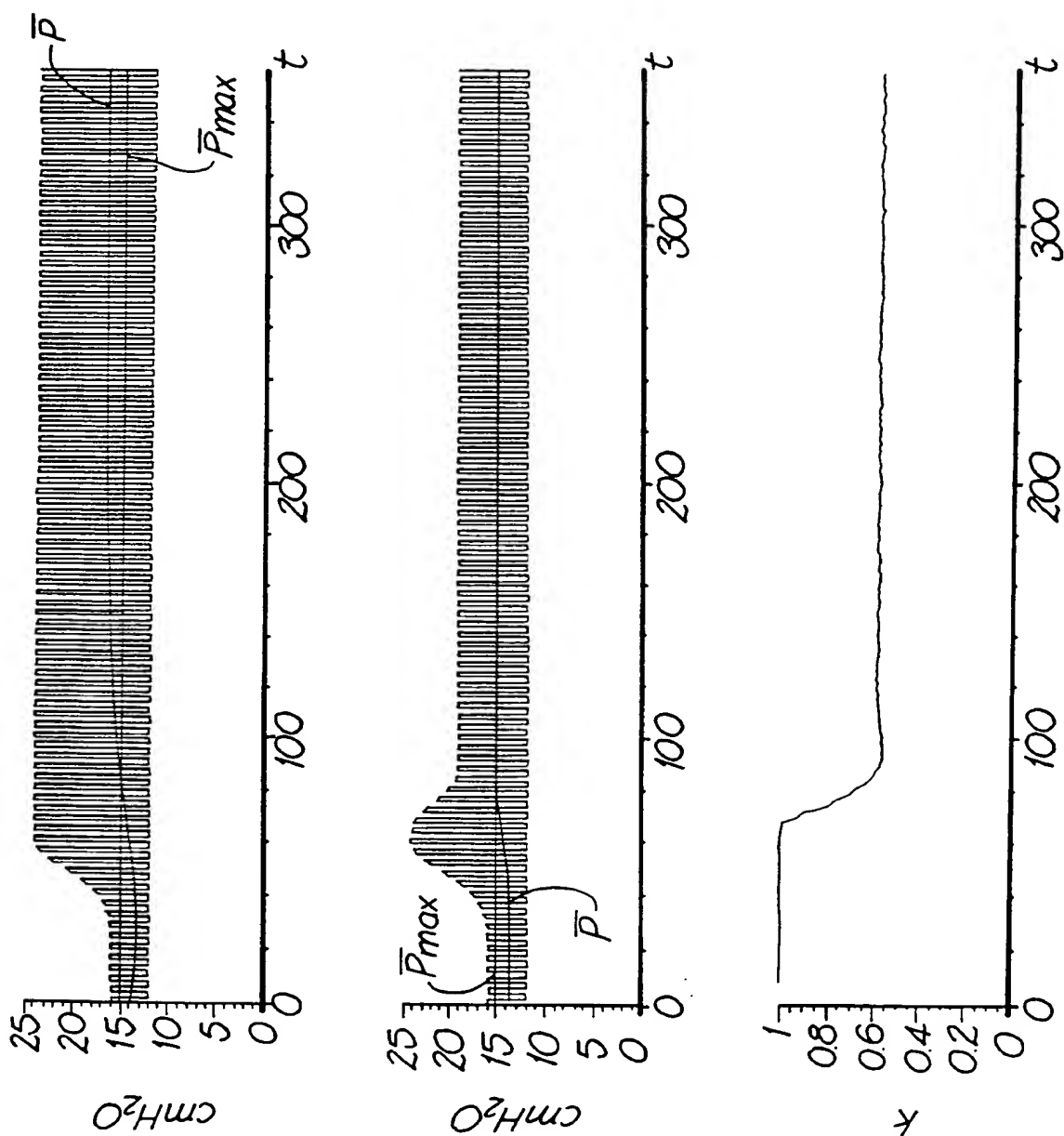


FIG. 3



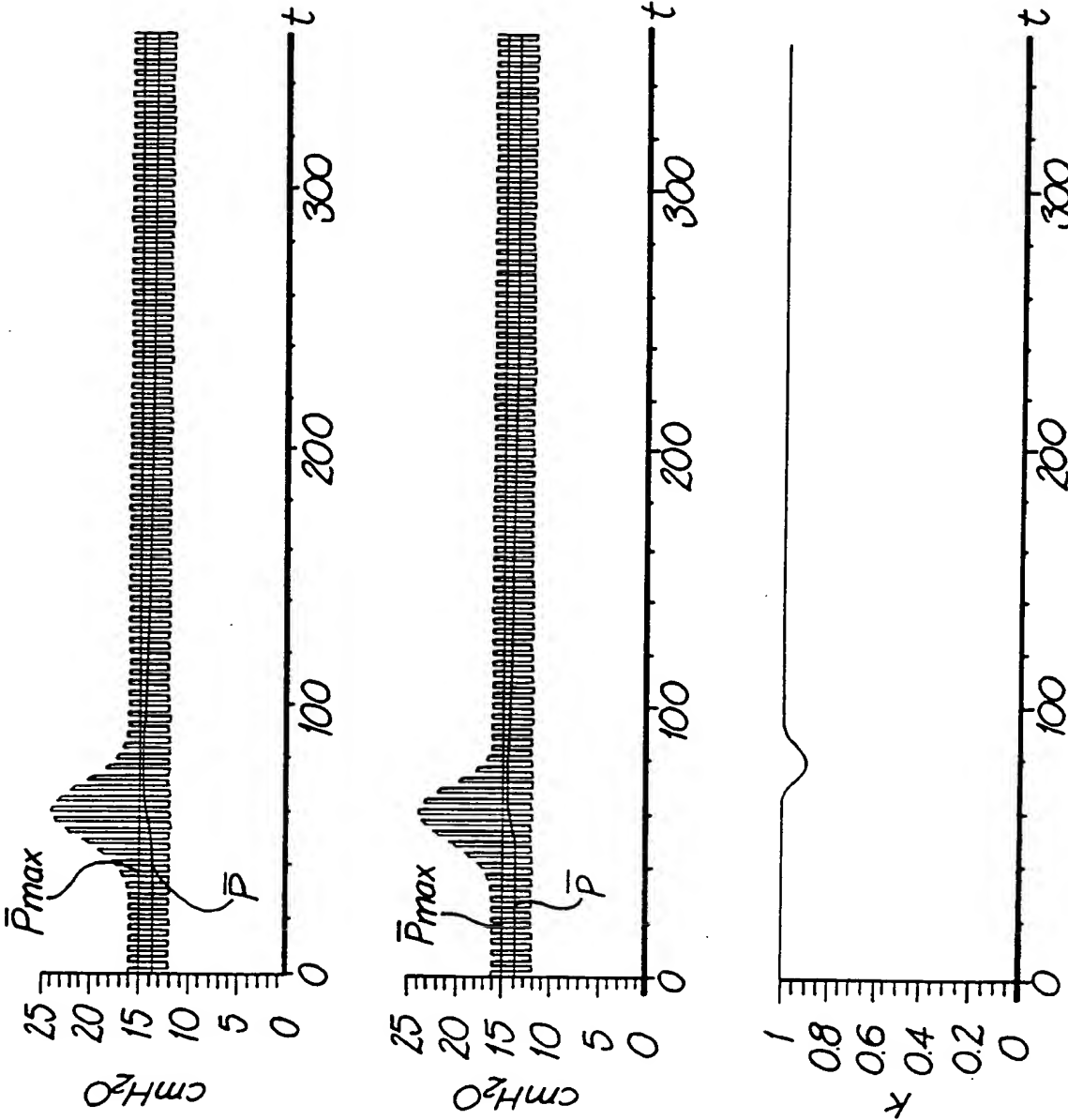
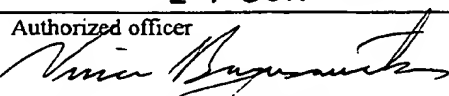


FIG. 4

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/AU00/00411

|  |  |  |  |   |   |  |   |  |  |   |  |  |
|--|--|--|--|---|---|--|---|--|--|---|--|--|
| <b>A. CLASSIFICATION OF SUBJECT MATTER</b>   |  |  |  |   |   |  |   |  |  |   |  |  |
| Int. Cl. <sup>7</sup> : A61M 16/00   |  |  |  |   |   |  |   |  |  |   |  |  |
| According to International Patent Classification (IPC) or to both national classification and IPC  |  |  |  |   |   |  |   |  |  |   |  |  |
| <b>B. FIELDS SEARCHED</b>  |  |  |  |   |   |  |   |  |  |   |  |  |
| Minimum documentation searched (classification system followed by classification symbols)<br>IPC: A61M 16/-  |  |  |  |   |   |  |   |  |  |   |  |  |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  |  |  |  |   |   |  |   |  |  |   |  |  |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>DWPI: A61M 16/- & keywords   |  |  |  |   |   |  |   |  |  |   |  |  |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>  |  |  |  |   |   |  |   |  |  |   |  |  |
| Category*  | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No.  |  |   |   |  |   |  |  |   |  |  |
| A  | WO 97/14462 A1 (UNIVERSITY OF FLORIDA) 24 April 1997   |  |  |   |   |  |   |  |  |   |  |  |
| A  | EP 425092 A1 (RESPIRONICS INC.) 2 May 1991   |  |  |   |   |  |   |  |  |   |  |  |
| P, A   | US 5901704 A (ESTES et. al.) 11 May 1999   |  |  |   |   |  |   |  |  |   |  |  |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex   |  |  |  |   |   |  |   |  |  |   |  |  |
| <p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&amp;" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table> |  |  | "A" document defining the general state of the art which is not considered to be of particular relevance | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention | "E" earlier application or patent but published on or after the international filing date | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone | "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art | "O" document referring to an oral disclosure, use, exhibition or other means | "&" document member of the same patent family | "P" document published prior to the international filing date but later than the priority date claimed |  |
| "A" document defining the general state of the art which is not considered to be of particular relevance   | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |  |  |   |   |  |   |  |  |   |  |  |
| "E" earlier application or patent but published on or after the international filing date  | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |  |  |   |   |  |   |  |  |   |  |  |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |  |  |   |   |  |   |  |  |   |  |  |
| "O" document referring to an oral disclosure, use, exhibition or other means   | "&" document member of the same patent family  |  |  |   |   |  |   |  |  |   |  |  |
| "P" document published prior to the international filing date but later than the priority date claimed   |  |  |  |   |   |  |   |  |  |   |  |  |
| Date of the actual completion of the international search<br>1 June 2000   |  | Date of mailing of the international search report<br>21 JUN 2000  |  |   |   |  |   |  |  |   |  |  |
| Name and mailing address of the ISA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaustalia.gov.au<br>Facsimile No. (02) 6285 3929   |  | Authorized officer<br><br>VINCE BAGUSAUSKAS<br>Telephone No : (02) 6283 2110 |  |   |   |  |   |  |  |   |  |  |

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No.  
**PCT/AU00/00411**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search<br>Report | Patent Family Member              |
|---|-----------------------------------|
| WO 9714462                                | AU 73686/96                       |
| EP 425092                                 | AU 38508/93 CA 2024477 JP 7016517 |
| US 5901704                                | AU 29268/92 EP 610405 WO 9308857  |
| END OF ANNEX                              |                                   |

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**  
(PCT Article 36 and Rule 70)

|  |   |  |
|--|---|--|
| Applicant's or agent's file reference<br>442612c   | <b>FOR FURTHER ACTION</b>   | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
| International Application No.<br>PCT/AU00/00411  | International Filing Date ( <i>day/month/year</i> )<br>5 May 2000 | Priority Date ( <i>day/month/year</i> )<br>6 May 1999  |
| International Patent Classification (IPC) or national classification and IPC<br><br>Int. Cl. <sup>7</sup> A61M 16/00 |   |  |
| Applicant<br>RESMED LIMITED et al  |   |  |

This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

|      |                                     |   |
|------|-------------------------------------|---|
| I    | <input checked="" type="checkbox"/> | Basis of the report   |
| II   | <input type="checkbox"/>            | Priority  |
| III  | <input type="checkbox"/>            | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| IV   | <input type="checkbox"/>            | Lack of unity of invention  |
| V    | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI   | <input type="checkbox"/>            | Certain documents cited   |
| VII  | <input type="checkbox"/>            | Certain defects in the international application  |
| VIII | <input type="checkbox"/>            | Certain observations on the international application   |

|   |   |
|---|---|
| Date of submission of the demand<br>1 November 2000   | Date of completion of the report<br>9 November 2000   |
| Name and mailing address of the IPEA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaustalia.gov.au<br>Facsimile No. (02) 6285 3929 | Authorized Officer<br><br>VINCE BAGUSAUSKAS<br>Telephone No. (02) 6283 2110 |

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☐ the description,        pages , as originally filed,  
   pages , filed with the demand,  
   pages , received on    with the letter of
- ☐ the claims,        pages , as originally filed,  
   pages , as amended (together with any statement) under Article 19,  
   pages , filed with the demand,  
   pages , received on    with the letter of
- ☐ the drawings,        pages , as originally filed,  
   pages , filed with the demand,  
   pages , received on    with the letter of
- ☐ the sequence listing part of the description:  
   pages , as originally filed  
   pages , filed with the demand  
   pages , received on    with the letter of

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description,        pages
- ☐ the claims,        Nos.
- ☐ the drawings,        sheets/fig.

**5. ☐ This report has been established as if (some of) the amendments had not been made; since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)). \*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

|                               |             |     |
|-------------------------------|-------------|-----|
| Novelty (N)                   | Claims 1-23 | YES |
|                               | Claims      | NO  |
| Inventive step (IS)           | Claims 1-23 | YES |
|                               | Claims      | NO  |
| Industrial applicability (IA) | Claims 1-23 | YES |
|                               | Claims      | NO  |

**2. Citations and explanations (Rule 70.7)**

All the documents cited in the ISR were category A only. Therefore the claimed invention is not disclosed in any of these patent documents and hence all the claims are novel.